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JUL 22 2011

Company	Crospon Ltd. Galway Business Park Dangan Galway, Ireland Tel – 011 [353] (91) 519882 Fax – 011 [353] (91) 519873
Official Contact:	John O'Dea, Ph.D.
Proprietary or Trade Name:	EndoFLIP® Gastric Tube EF-900
Common/Usual Name:	Gastrointestinal motility monitoring system
Classification / CFR:	KNT – CFR 876.1500
Device:	EndoFLIP® Gastric Tube EF-900
Predicate Devices:	K002838 – BioEnterics® Gastric Balloon Suction Catheter

Device Description:
The EndoFLIP® Gastric Tube is a simple single lumen tube which acts as a support bougie for a 43 Fr lumen and may be used to aid in the EndoFLIP® catheter, K092850 and K102214, deployment. It may also be used for drainage, suction or irrigation as it is open at both ends and features a number of side-holes at the distal end. A connector is supplied to push-on the proximal end to aid attachment to a suction system. The tube is 75 cm long and markings are provided at 20 cm and 70 cm from the distal end. The EndoFLIP® Gastric Tube is supplied non-sterile and is single patient use, disposable. An alcohol swab is provided to wipe down the tube exterior prior to use.

Indications for Use:
The EndoFLIP® EF-900 Gastric Tube is intended for use in bariatric surgical procedures to provide a sized support bougie, and to permit stomach decompression, gastric fluid drainage and removal. It is also intended for use to aid deployment of EndoFLIP® EF-620, EF-325, and BF-325 catheters.

Patient Population:	Patients undergoing gastric and bariatric surgery where a bougie or suctioning capabilities are needed.
Environment of Use:	Hospitals and Surgery Centers
Contraindications:	None

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	EndoFLIP® Gastric Tube EF-900	BioEnterics® Gastric Balloon Suction Catheter K002838
Attributes		
Indications for Use	The EndoFLIP® EF-900 Gastric Tube is intended for use in bariatric surgical procedures to provide a sized support bougie, and to permit stomach decompression, gastric fluid drainage and removal. It is also intended for use to aid deployment of EndoFLIP® EF-620, EF-325, and BF-325 catheters.	Indicated for use in gastric and bariatric surgical procedures to provide visible and tactile delineation of the antrum of the stomach along with the ability to decompress and remove gastric fluid and size a gastric pouch.
Typical Use	Use in gastric and bariatric surgical procedures	Use in gastric and bariatric surgical procedures
Environments of use	Hospital and surgery centers	Hospital and surgery centers
Patient Population	All individuals undergoing gastric and bariatric procedures	All individuals undergoing gastric and bariatric procedures
Contraindications	None	None
Prescription	Prescription use	Prescription use
Functions	Suction Drainage	Suction Drainage
Intraoperative use	Yes	Yes
French Size	43 Fr	40 – 56 Fr
Design		
Tube	Length -750 mm 14.3 mm OD	Length - 685 mm 13.3 mm OD
Side holes at distal end for suctioning	Yes	Yes
Depth markings	Yes	Yes
Connector for suction	Yes	Yes
Sterility	Supplied non-sterile, and are single patient use, disposable	Supplied non-sterile, and are single patient use, disposable
Performance	Age testing	N/A
Materials used	Tube – PVC with Duraglide/PTFE coating	Not identified
Biocompatibility	Tested according to ISO 10993-1	ISO 10993-1

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Substantial Equivalence:
The EndoFLIP® Gastric Tube is viewed as substantially equivalent to the predicate device because:

Indications –
Similar to predicate – K002838 – BioEnterics® Gastric Balloon Suction Catheter - Indicated for use in bariatric surgical procedures to provide a sized support bougie, and to permit stomach decompression, gastric fluid drainage and removal. In both cases the intended use is to assist the clinician in gastric and bariatric procedures.

It is also intended for use to aid deployment of EndoFLIP® EF-620, EF-325, and BF-325 catheters.

Technology –
Similar to predicate – K002838 – BioEnterics® Gastric Balloon Suction Catheter except the proposed device does not have a balloon which is unnecessary for the intended use i.e. the balloon is specifically purposed for sizing the pouch created during a gastric band placement, whereas the EF-900 is not used for the creation of such pouches.

Materials –
The materials in contact with the patient have been tested per ISO 10993.

Environment of Use –
Identical to predicate –K002838 – BioEnterics® Gastric Balloon Suction Catheter.

Patient Population –
Identical to predicate – K002838 – BioEnterics® Gastric Balloon Suction Catheter.

Performance Testing -
We did perform age testing, ISO 10993 testing for material biocompatibility, and a kink test. The proposed device meets its performance specifications and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Crospon, Ltd.
% Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL .34134-2958

JUL 22 2011

Re: K110529
Trade/Device Name: EndoFLIP® EF-900 Gastric Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: June 17, 2011
Received: June 20, 2011

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K110529

Device Name: EndoFLIP® EF-900 Gastric Tube

Indications for Use:

The EndoFLIP® EF-900 Gastric Tube is intended for use in bariatric surgical procedures to provide a sized support bougie, and to permit stomach decompression, gastric fluid drainage and removal. It is also intended for use to aid deployment of EndoFLIP® EF-620, EF-325, and BF-325 catheters.

Prescription Use (XX) **or** **Over-the-counter use** __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110529